Remarks

Claims 1-10 were pending in the subject application. By way of this Amendment, claim 1 has been amended. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-10 are currently before the Examiner for his consideration. Favorable consideration of the pending claims is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of Applicants' agreement with or acquiescence to, the rejections of record. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The Office Action indicates that the drawings and the specification have been objected to for the introduction of new matter into the disclosure.

Regarding the tapered distal section, applicants respectfully assert that the tapering of the distal section is not new matter. Rather, it was well known in the art at the time of the invention that in order to conduct or guide catheters through vessels, a guidewire may have a tapering at its distal end. The claimed invention relates to a guidewire that is MRI compatable and has a metallic wire distal part and an MRI-inert plastics part. The end of the distal part can be of any shape such that the guidewire is able to guide catheters inside human or animal vessels. Moreover, "a patent drawing does not define the precise proportions of the elements depicted and thus may not be relied on to show particular distances or sizes when the specification is completely silent in that respect." In re Heinle, 342 F.2d 1001, 1007; 145 U.S.P.Q. 131 (52 C.C.P.A. 1164, 1172) (1965) (citing In re Olson, 212 F.2d 590; 101 U.S.P.Q. 401 (41 C.C.P.A. 871)). Therefore, the tapered distal section, as shown in new Figures 2, 3, 4, and 5, does not introduce new matter into the disclosure. In addition, please note that the claims do not include a limitation regarding the extent of tapering of the distal end.

Regarding Figures 2A and 2B, applicants respectfully assert that the tapering connection using glue is not new matter. Rather, the original specification at page 3, first paragraph, states, in

pertinent part, "[t]he connection **3** can be designed in different ways . . . [i]t could be a gluing or the main part 4 is pinched over or under the distal front part 2 at the connection. . . as well as a diminution of the main part at its front end which could then lead into the interior of the distal part **2** and be glued or pinched therein." Accordingly, Figures 2A and 2B do not introduce new matter into the disclosure.

Regarding Figure 3, applicants respectfully assert that the means for pinching the distal part onto the main part is not new matter. Original claim 4 discloses that the distal part is pinched onto the main part. An ordinary person skilled in the art at the time the invention was made would understand that Figure 3 illustrates a distal part pinched onto the main part. Accordingly, Figure 3 does not introduce new matter into the disclosure.

Submitted herewith is a proposed new Figure 4. Regarding proposed new Figure 4, applicants respectfully assert, as discussed above in reference to Figures 2A and 2B, that a tapered connection between the main part and the distal part shown is not new matter. However, proposed new Figure 4 has been amended to show an embodiment without a tapered connection between the main part and the distal part. No new matter has been introduced into the disclosure by this proposed new Figure.

Regarding the written description, replaced paragraph at page 3, line 1, and replaced paragraph at page 3, last paragraph refer to the new Figures, which as discussed above, do not introduce new matter.

Regarding the introduction of "crimps" and "Crimp" in the specification, applicants have removed such references and replaced such references with "pinching means". Support for this amendment can be found, at least, at page 3, lines 1-2 and original claim 5. No new matter has been introduced by these amendments.

Regarding the introduction of "Shrink-tube" in the specification, applicants have removed such a reference and replaced the reference with "Shrink down plastic tubing". Support for this amendment can be found, at least, at original claim 6. No new matter has been introduced by this amendment.

Regarding the term "Core" in the specification, applicants assert that support can be found, at least, at original claims 7 and 10.

Regarding the term "Glue", support can be found through the terms "gluing" and "glued", which are described in the specification at page 3, first paragraph, and original claim 4. Glue is the term for a substance that glues two elements together. No new matter has been introduced by this amendment.

Accordingly, applicants respectfully request reconsideration and withdrawal of the objections to the specification and the drawings under 35 U.S.C. § 132(a) and 37 C.F.R. § 1.83(a).

Claims 1, 3, 4, 7, 9, and 10 have been rejected under 35 USC §102(b) as anticipated by Johanson *et al.* (U.S. Patent No. 5,596,996). Applicants respectfully traverse this rejection.

The Office Action, at page 3 paragraph 6, states that "Johanson *et al.* discloses an MRI compatible device for guiding catheters having a metallic wire distal part (45) and an MRI-inert plastics main part (col. 4, line 3-42). The distal part and the main part are glued together (col. 5, line 24). The main part comprises a core comprising an insulant material (col. 4, lines 37-42). The main part comprises an artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (col. 4, lines 37-42)."

However, the Johanson *et al.* reference does not disclose an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part as claimed in claim 1. Rather, the Johanson *et al.* reference teaches, at col. 4, lines 3-4, "tube **30** is supported by a distally tapering core wire **25** . . . [t]he core wire **25** can be constructed of stainless steel" (underline added for emphasis). The long stainless steel core wire of the Johanson *et al.* reference would cause artifacts in an MR image and does not suggest use in an MRI system. Furthermore, a stainless steel core wire is not an inert plastics main part. In addition, the Johanson *et al.* reference, at col. 3, lines 17-31, discloses "[p]rior art guidewires are currently constructed with a spring coil over the tapered distal end of the core wire . . . [i]nstead of a spring coil, however, applicant's guidewire **20** is constructed using a tube **30** which can be made of an elastomer or an alloy which is highly flexible without permanent deformation such as a shape memory alloy . . . [a] preferred embodiment uses NiTi 49-51 atom % Ni" (underline added for emphasis). For the preferred embodiment, the tube of the Johanson *et al.* reference is not an MRI-inert plastics main part, nor is it a metallic wire distal part.

The Johanson *et al.* reference does not teach a metallic wire distal part as claimed in claim 1 of the subject application. Rather, the Johanson *et al.* reference, at col. 5, lines 21-26, teaches "radiopaque marker band **45** can be placed in the distal inner lumen of the tube **30** approximately 1-2 cm from the tip **40** enabling the physician to visualize the progress of the tip **40** under fluoroscopy . . . [t]he marker band **45** can be attached by heat bonding or with an adhesive such as epoxy." Instead of a metallic wire distal part, marker band **45** is a radiopaque band. The marker band **45** of the Johanson *et al.* reference is designed for x-ray imaging, not MRI.

Accordingly, the Johanson *et al.* reference does not teach an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part as claimed in claim 1, 3, 4, 7, 9, and 10.

Claims 1-5 and 7-10 have been rejected under 35 USC §102(e) as anticipated by Muni *et al.* (U.S. Patent No. 6,375,629). Applicants respectfully traverse this rejection.

The Office Action, at page 5 paragraph 8, states that "Muni *et al.* discloses an MRI compatible device for guiding catheters having a metallic wire distal part (26) comprising nickel titanium or stainless steel (col. 5, lines 8-10), and an MRI-inert plastics main part (12; col. 4, lines 29-30). The distal part is pinched with the main part (col. 5, lines 45-47). The main part comprises a core comprising an insulant material (12; col. 4, lines 29-30). The main part comprises and artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (12; col. 4, lines 29-30). Additionally, Muni *et al.* discloses a metallic wire distal part (32) glued to the main part (col. 5, lines 27-30)."

However, the Muni *et al.* reference does not teach or suggest an MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part, as claimed in amended claim 1.

Rather, the Muni *et al.* reference, at col. 5, lines 23-36, teaches "[a]s shown in FIG. 2, coil **32** is provided around the core wire **26** . . . [c]oil **32** is formed of a suitable radiopaque material such as gold, platinum, or a platinum alloy" (underline added for emphasis). The radiopaque material teaches or suggests use in an x-ray system, not an MRI system. The coil **32** taught by the Muni *et al.* reference is not MRI compatible. Therefore the Muni *et al.* reference does not teach or suggest an

MRI compatible device for guiding catheters inside human or animal vessels, comprising a metallic wire distal part and an MRI-inert plastics main part, as claimed in amended claim 1

Accordingly, reconsideration and withdrawal of the rejections of claims 1-5 and 7-10 under 35 USC §102(b) is respectfully requested.

Claims 1-4, 7, 8, and 10 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/42268 to Cordis Corporation. The applicants respectfully traverse this grounds for rejection.

The Office Action states, at page 5, that:

> "Cordis Corporation discloses an MRI compatible device for guiding catheters (Page 5, lines 7-10) having a metallic wire distal part (3) comprising nickel titanium or stainless steel (Page 6, lines 14-16), and an MRI-inert plastics main part (7). The main part comprises an artificial material (Page 6, lines 5-6). The metallic wire distal part is glued to the main part (Page 6, line 19; Figure 2). Cordis Corporation discloses a core (5) in the center of the main part comprising an insolent material."

However, the Cordis Corporation does not disclose an MRI compatible device for guiding catheters having a metallic wire distal part and an MRI-inert plastics main part. Rather, the Cordis Corporation reference teaches a guidewire having a glass body **5** (see page 5, lines 14-23). The Cordis Corporation could have considered plastics for the body, as evidenced at page 6, lines 13-14, which teaches, "the distal top portion 3 of the guidewire may be formed of a plastic", yet the body is taught to be glass.

Therefore, reconsideration and withdrawal of the rejection of claims 1-4, 7, 8, and 10 under 35 U.S.C. §102(b) is respectfully requested.

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Muni *et al.* (U.S. Patent No. 6,375,629) as applied to claim 1 above and further in view of Ryan *et al.* (U.S. Patent No. 5,492,532). The applicants respectfully traverse this grounds for rejection. The deficiencies of the Muni *et al.* reference have been discussed above with respect to the rejection of claim 1, from which claim 6 depends. The Ryan *et al.* reference does not cure such defects. The Muni *et al.* and Ryan *et al.* references, alone or in combination, do not teach or suggest the subject invention as claimed in claim 6. Accordingly, applicants assert a prima facie case of obviousness has

not been presented with respect to claim 6. Therefore, reconsideration and withdrawal of the rejection of claim 6 under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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JSP/lkw/sjk
Attachment: Petition and Fee for Extension of Time

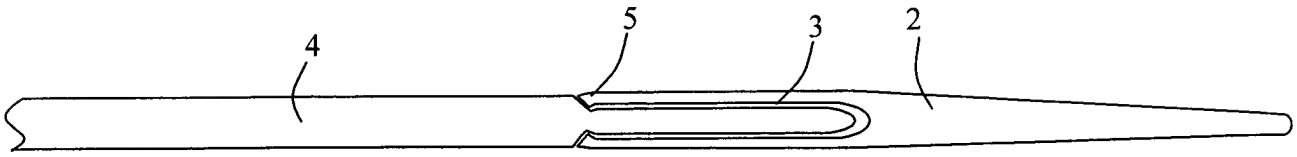

Fig. 3

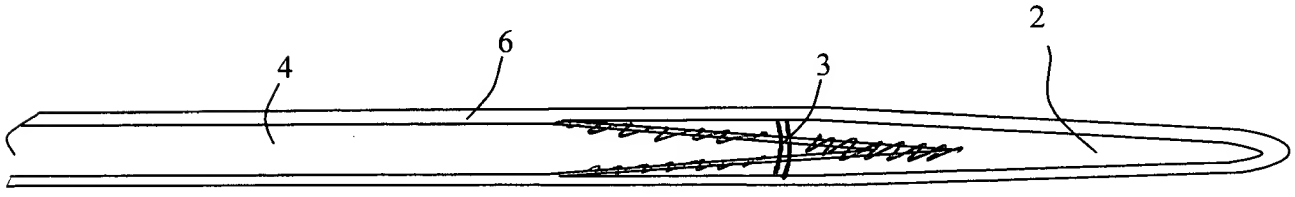

Fig. 4